

# 1<sup>st</sup> CENTER OF PLANO

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August 3, 1999

Documents Branch  
Food & Drug Administration  
5630 Fishers Lane #1061  
Rockville, MD 20852

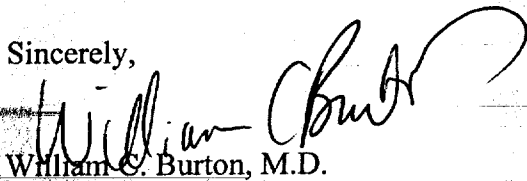
Dear Sirs:

We have recently been advised of the draft proposing mandatory implementation of a look back program for patients who have received units of blood from donors subsequently found to be hepatitis C positive. We understand that this program would extend indefinitely into the past.

As Medical Director of the Blood Bank and Medical Center of Plano, I am strongly opposed to this recommendation. Our experience with previous look back programs have revealed minimal benefit and large cost. In addition, patient population to whom we must communicate these findings is usually elderly and are terrified by the implications of these tests. I consider this notification to such patients as cruel and inappropriate. They are unable to understand that no efficacious therapy currently exists and there is no means to "cure" them.

I strongly advise reconsideration of this ill advised requirement.

Sincerely,



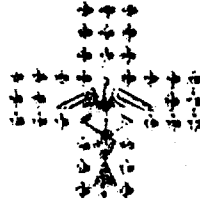
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WCB:sau

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# Dallas-Fort Worth Hospital Council



*John C. Gavras, President*

July 21, 1999

Documents Branch  
Food & Drug Administration  
5630 Fishers Lane #1061  
Rockville, MD 20852

The Dallas-Fort Worth Hospital Council represents 82 hospitals in the metroplex area. On behalf of those member hospitals, I am writing you in regards to a draft guidance document (HFA-305) that proposes health providers initiate a HCV Lookback Program using a 1990 HCV test. The draft document also proposes providers "search historical records dating back indefinitely to the extent that electronics or other readily retrievable records exist."

I have followed the most recent requirement of a HCV Lookback (1992 test). This Lookback required going back to a date of January 1988, not an indefinite period of time. This particular Lookback produced negligible results and caused undue concern and fright among senior citizens. The following results of this Lookback, as it pertains to one medical center, are indicative:

- 1) 528 units of blood were identified for final disposition.
- 2) 67% of those recipients identified had expired for non-related medical conditions.
- 3) A large number (123) tested positive before and after their blood transfusion. Therefore, the transfusion was not the cause of the positive test results.
- 4) The process finally focused on 20 recipients who were HCV positive. A great majority were senior citizens. Their responses to being informed were negative. They included:
  - "Does this mean I won't be able to move to the nursing home?"
  - "I am retiring from work; does this mean it will take all my retirement money to cure me?"

Many of these senior citizens do not understand being informed about a medical condition that is not curable. They are not happy nor grateful. They are scared.

We understand the draft document (1990 test) shows a high percentage of false positive results. Another reason the proposed Lookback should not be initiated.

July 21, 1999

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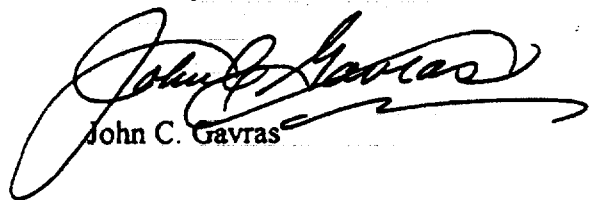
Please allow me to emphasize again, the 1992 Lookback produced negligible results. Senior citizens have all the medical worries they can handle. They do not comprehend being told they cannot be cured. When they convey their fears, I can assure you that moment in their lives can only be described as cruel.

I believe you will agree with our member hospitals that all Lookback proposals need to be evaluated weighing the benefits to the patient. This is one that doesn't seem to pass the test. We do not believe the 1990 Lookback is justified.

To end this communication on a positive note, may we suggest the FDA consider patients that visit a hospital or physician's office revealing a blood transfusion in their past be tested for Hepatitis C. Why not consider a HCV test when a consumer goes to their physician for an annual physical? With the increase in the number of tattoo establishments, can we investigate some accountability regarding Hepatitis risks?

There has to be a better and more sensitive way to address this issue. Thank you for your consideration of the above.

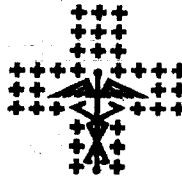
Sincerely,



John C. Gavras

cc: Robin Biswas, M.D.  
Laboratory of Hepatitis (HFM-325)  
FDA-CBER  
1401 Rockville Pike  
Rockville, MD 20852

Dallas-Fort Worth Hospital Council



John C. Gavras, President

RECEIVED

JUL 28 1999

ADMINISTRATION

MEMORANDUM

TO: DFWHC Members  
FROM: John C. Gavras *[Signature]*  
DATE: July 22, 1999  
SUBJECT: FDA Document (Draft), dated June 1999

*copy to  
Freaka -  
Please distribute  
to everyone to  
write letters -  
I plan on doing  
also - Is there  
anyone else to  
include?  
Betty*

In the not-too-distant past, the FDA required providers to initiate an HCV (Hepatitis C Virus) Lookback program based on a 1992 test. Providers were required to look back as far as 1988.

One large hospital in the Dallas-Fort Worth metroplex documented the results of its effort to find former patients that received a blood transfusion back to 1988. Here are some of their results:

- 1) 528 units of blood were identified for final disposition.
- 2) Subtracting those patients who received multiple units, the medical center had to contact 471 different recipients.
- 3) Of the 471 recipients, 315 (67%) had expired from non-related medical conditions.
- 4) Of the 156 remaining recipients, 123 tested positive before and after the blood transfusion. Therefore, the blood transfusion was not the cause of their positive test results.
- 5) The process boiled down to 20 recipients out of 471 who were HCV positive. Most of these recipients were elderly people. When told, they became frightened to the point of panic. One woman thought this was going to preclude her moving into a rest home for the elderly. Another individual said, "I feel good; I am preparing to retire next week from my job. Does this mean it will take all my retirement money to cure me?" Worse yet, after informing an elderly patient ... how do you answer the question, "What do I need to do to get cured?"

My purpose for writing is to inform you the FDA now has a draft document in circulation that will take a 1990 HCV test (which I am told has 75% false-positive results) and require providers to initiate a lookback to the beginning of time. Yes, you read it correctly ... the record search "should be of historical testing records dating back indefinitely to the extent that electronic or other readily retrievable records exist."

The aforementioned medical center researched their cost for the 1992 HCV Lookback with a cut-off date of January 1988. The 12-14 month experience cost an approximate \$100 per patient. Calculate the new proposed Lookback which dates back indefinitely.

If there was ever a time you need to communicate with the FDA ... this is it. Your silence will be interpreted as approval of the proposed draft.

Write a note that communicates the proposal is costly, provides no benefits, and scares the elderly population. If the FDA was serious, the most logical approach to HCV Lookback includes the following fact and suggestions:

**FACT:** An estimated 5% of the population has Hepatitis C. You get it the same way you get Hepatitis A and B.

**SUGGESTION:**

- 1) If a patient goes to a hospital and/or physician office and reveals they have had a blood transfusion, a test for Hepatitis C is appropriate and necessary.
- 2) When the consumer goes to the physician office for a physical, again, a test for Hepatitis C seems appropriate.

Sounds too logical ... at least, for the minds that sit around a desk devising Lookback programs that are meaningless.

Well, so much for the background information. What do you need to do? Same ole' answer. Communicate to:

**Documents Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, #1061  
Rockville, MD 20852**

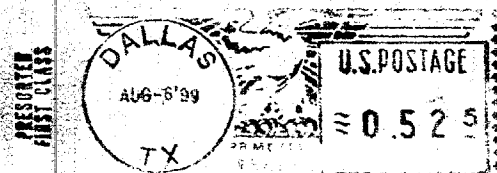
Let them hear from you before August 20th.

**Attachment: Council's Letter to FDA**

**cc: Conference of Metropolitan Hospital Associations  
AHA Region VII Members  
AHA - Washington, D.C. Office  
Dr. Robin Biswas  
Laboratory of Hepatitis (HFM-325)  
FDA-CBER  
1401 Rockville Pike  
Rockville, MD 20852**

# MEDICAL CENTER OF PLANO

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